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In Reply to Office Action of November 4, 2003

<u>REMARKS</u>

Claims 6-9 and 11-31 are pending. Claims 15 and 18 have been withdrawn from

consideration. Independent Claim 6 has been amended to require a particular range of

component (A) and component (B). Support for these ranges is found in the specification at

page 7, line 25-page 8, line 3 and page 8, lines 23-27. Accordingly, the Applicants do not

believe that any new matter has been added.

The Applicants thank Examiner Coe for the courteous and helpful discussion on

January 8, 2004. It was suggested that the Applicants further distinguish any anti-

hypertensive effects provided by chlorogenic acid as disclosed by the cited prior art: Cheng

et al., Chinese Pharm. J. (1994) and Ahn, U.S. Patent No. 4,981,852. These documents are

distinguished below. Additionally, independent Claim 6 has been amended further

distinguishing the invention from these documents. Favorable consideration and allowance

of this application is respectfully requested.

Election/Restriction

The Applicants thank Examiner Coe for rejoining Claims 8, 11-14 and 16-17.

Applicants previously elected the species (A) chlorogenic acid and (B) organic acid (lactic

acid). Upon an indication of allowability for the elected species the Applicants understand

that examination will be extended to other species.

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### Rejection—35 U.S.C. 103

Claims 6-9, 11-14, 16, 17 and 19-31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cheng et al., Chinese Pharm. J. 46:575 and Ahn, U.S. Patent No. 4,981,852. The cited prior art documents do not anticipate the claimed invention, because neither document discloses or suggests the combination of chlorogenic acid and an organic acid for the treatment of hypertension. Moreover, there is no suggestion in either document for the particular concentration ranges of chlorogenic acid and the organic acid now required by independent Claim 6. As disclosed on page 3, lines 10-15 of the specification, the present inventors have found that the combination of chlorogenic acid and an organic acid markedly inhibits the rise of blood pressure compared to the single use of these compounds.

Cheng et al., Table 1, only disclose that chlorogenic acid reduces arterial blood pressure in spontaneously hypertensive rats by  $-24.9 \pm 5.6$  mmHg at an ED50 of  $10.1 \pm 2.6$ mg/kg. The vehicle used by Cheng is Locke Ringer Solution, see page 577, 9<sup>th</sup> line from page bottom, which according to Dorland's online Medical Dictionary (attached) does not contain an organic acid. Therefore, Cheng does not anticipate the claimed invention, nor provide any suggestion that the combination of chlorogenic acid and an organic acid, specifically lactic acid, would exert significant antihypertensive effects.

Ahn is cited as describing lactic acid and does not disclose chlorogenic acid. However, this document only discloses that lactic acid along with other glycols helps dissolve an anti-hypertensive drug: triamterene. See col. 1, lines 58-59: "The invention contemplates the solubilization of triamterene in a combination of glycols and lactic acid." Col. 1, lines 14-16 describe the anti-hypertensive properties of triamterene. Ahn does not suggest that lactic

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acid itself has any effect on hypertension. Thus, while the combination of lactic acid and glycols helps solubilize the antihypertensive drug <u>triamterine</u>, there is no suggestion in the cited prior art for combining lactic acid (or an organic acid) with <u>chlorogenic acid</u> in order to treat hypertension. Accordingly, the Applicants respectfully request that this rejection be withdrawn as the cited prior art does not disclose or suggest the claimed invention.

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#### **CONCLUSION**

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,

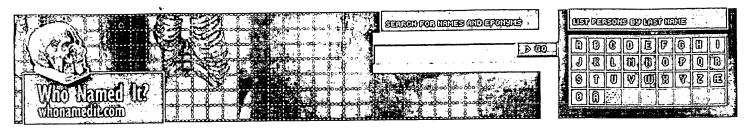
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Locke-Ringer solution

Also known as: Locke's solution

Associated persons: <u>Frank Spiller Locke</u> <u>Sydney Ringer</u>

Description:

An isotonic electrolytic infusion solution - the same as Ringer solution. It is used in experiments in physiology. It contains sodium, potassium, calcium, and magnesium chlorides; sodium bicarbonate, dextrose, and water.

See Ringer's solution, under Sydney Ringer, British physiologist, 1835-1910.

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